

DECLARATION OF ELIZABETH LEE

I, Elizabeth Lee, do hereby declare as follows:

1. I am over eighteen years of age and am competent to testify regarding the matters stated in this declaration. I give this declaration voluntarily. I have not been promised any benefit, been coerced, or been threatened in any manner in exchange for the testimony in this declaration.

2. In November 2015, I was hired by Covance Inc. ("Covance") to work as a Clinical Research Associate ("CRA").

3. Prior to starting at Covance, I had worked as a CRA for approximately eight months for another company. I have a Bachelor of Science in clinical research.

4. Covance is a company that contracts with pharmaceutical companies to help in the development of drugs and medical devices. The overall responsibility of a CRA at Covance is to monitor and supervise clinical medical research trials, which test the safety and effectiveness of new drugs and medical treatments. Although CRAs do not actually conduct the trial, CRAs oversee and manage all aspects of clinical trials.

5. Clinical research trials are broken up into several different phases. Each phase requires the participation of CRAs. Some CRAs are assigned to particular phases, while others work on all types of phases. In my case, I have the most experience in Phase II, which is a phase that evaluates the efficacy, safety, and dosage specifications of new drugs. Phase II trials are often targeted at patients afflicted with the condition the drug is intended to treat.

6. As a CRA, I am assigned to one study at a time but I could be assigned to more than one study depending upon the complexity of the study. I typically do not work directly with other CRAs as I manage my own clinical sites but I do speak with other CRAs who

are assigned to the same clinical study to exchange ideas and feedback. At this time, I manage thirteen clinical trial sites.

7. My job responsibilities as a CRA include site management, database management, training investigators, reviewing patient data and ensuring patient safety. I am in regular contact and field questions from the clinical sites that I am assigned to and regularly visit the sites.

8. The requirements of a trial are set forth in a written protocol that is prepared by the pharmaceutical company that is Covance's client, in accordance with regulations established by the Food and Drug Administration. The protocol sets forth the objectives of the trial, the methods by which the trial is designed to operate, and procedures that must be followed in order to safeguard the health of participants and certain metrics to assess the effectiveness of the clinical trial.

9. I do not perform routine data entry or any significant clerical tasks as part of my job as a CRA. I do utilize the Company's Clinical Trial Management Software ("CTMS") system to prepare written reports that summarize the status of the clinical trials that I am assigned to. After each clinical site visit, I am required to prepare a report that details any issues the clinical site may have regarding data entry or patient safety. These reports reflect the steps I take to supervise and manage the clinical trials.

10. I spend most of my work hours visiting clinical trial sites, traveling to clinical trial sites, or preparing for those visits by reviewing the protocols for the particular clinical trials I am working on.

11. My travel schedule varies significantly and depends upon the nature and complexity of the clinical trial sites to which I am assigned. The percentage of my time spent

traveling depends on the location of the clinical trial site(s) that I am monitoring and the amount of data. I have autonomy over my schedule because I set clinical site visits with the clinical site directly.


12. My work schedule significantly varies depending upon the week and depending upon the clinical trial, the clinical trial's protocol, and the clinical trial sites that I am assigned to. I usually travel between Monday and Thursday to clinical sites. As a result, my day-to-day schedule varies.

13. I am free to take breaks whenever I want for as long as I like. I decide if and when I need a break and for how long. My supervisor does not know or set my break or work schedule. Brief errands during the day are permitted and I do not have to ask my supervisor but out of courtesy, I do notify her.

14. Because I work out of my home, I do not have daily contact with the supervisor that I report to. I have a monthly meeting with my supervisor but can contact her as needed. My supervisor does not set or manage my schedule.

15. I declare under penalty of perjury that the foregoing statement is true and correct.

Executed on this 3rd day of November, 2017 in Durham, NC.



ELIZABETH LEE